

**REMARKS**

Applicants submit herewith a Request for Continuing Examination and a Rule 1.132 Declaration of Dr. Ignacio Blanco Blanco. The Declaration submitted herewith is unexecuted; an executed Declaration will follow shortly. Dr. Blanco is the author of the principal cited reference and also the lead investigator for the study giving rise to the study allegedly constituting a public disclosure of the associated research, and thereby allegedly anticipating the claimed invention. Applicants traverse the rejection for reasons previously made of record, and further supported by the Declaration of Dr. Blanco.

As shown by the Declaration of Dr. Blanco, the information relating to the patients treated by Dr. Blanco is not publicly available information. Thus, any treatment coinciding with the claimed invention, cannot be said to have been publicly disclosed or in public use within the U.S. by virtue of the information contained within the Registry. Further, to the extent that the information relating to the claimed invention was contained within the Registry, it was accessible only by the registering doctor, i.e., Dr. Blanco. Accordingly, the entry of information pertaining to treatment of the patients referred to in the Blanco reference does not destroy the patentability of the claimed invention.

Moreover, even assuming that the Registry information had become available, Dr. Blanco's Declaration demonstrates that the Registry does not contain information pertaining to the effect of the substitutive treatment for AAT deficiency or use of AAT for other conditions such as fibromyalgia. Although it appears from the confidential information of the Registry, available only to Dr. Blanco, it states only that the patients have received substitutive treatment, and the nature of that treatment and its

results were not included within the Registry, nor was such information publicly available.

Dr. Blanco's Declaration also addresses the report entitled "Ongoing Research in Europe: Alpha One International Registry (AIR) Objectives and Development", *Eur Respir J* (2007) 29:582-586. Dr. Blanco confirms that, although the AIR has various objectives, it is clear that much of the information contained within the AIR is carefully screened to protect and preserve the confidentiality of the various patients. Additionally, there is nothing within the report to suggest that the AIR is used in any way to disclose the details of substitutive treatment, or the characteristics of such substitutive treatment. Finally, Dr. Blanco's Declaration and the report make it clear that the purpose of AIR is to assemble information pertaining to Alpha One Anti Trypsin Deficiency, and not to disclose treatments that might be applicable to other conditions. Thus, there remains nothing in the record to support the proposition that the Blanco reference or related clinical studies constituted a publication or public use of the invention under 35 U.S.C. § 102.

In view of the foregoing and the attached supporting information, applicants respectfully submit that the rejection over the AIR and Spanish AAT Registries is overcome. Reconsideration and withdrawal of those rejections is respectfully requested in favor of a notice of allowability on the merits.

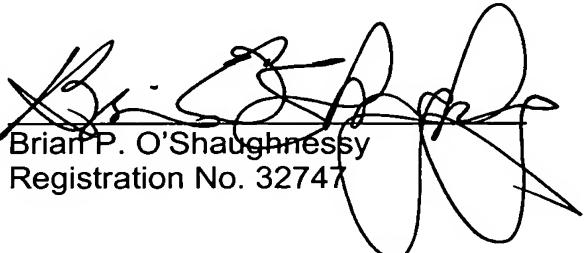
If, however, the Examiner perceives any impediments to such a formal notice of allowability, applicants encourage the Examiner to contact their attorney at the number provided below. Such informal communication will expedite examination and disposal of the case.

Respectfully submitted,

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